

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of

Sandrine SEGURA et al.

Application No.: 09/881,686

Filed: June 18, 2001

For: O/W EMULSION COMPRISING  
MICRONIZED BIOLOGICALLY ACTIVE  
AGENTS

) **MAIL STOP RCE**

) Group Art Unit: 1617

) Examiner: Shengjun Wang

) Confirmation No.: 9187

**SECOND INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, the accompanying information is being submitted in accordance with 37 C.F.R. §§ 1.97 and 1.98. Applicants request consideration of the documents listed on the accompanying Form PTO-1449, which were cited during prosecution of the corresponding Japanese application or which are counterparts of the documents cited in Japan.

This statement, Form PTO-1449 and listed documents are being submitted before the mailing of a first Office Action after the filing of a Request for Continued Examination under 37 C.F.R. § 1.114. Continued examination is requested and the fee required under 37 C.F.R. § 1.17(e) accompanies the present submission.

Many of the documents listed on the accompanying Form PTO-1449 are not in English. The following remarks are offered with respect to the non-English documents:

FR 2,521,565 corresponds to Redziniak et al. U.S.P. 4,508,703, a copy of which is provided to serve as an English translation. In addition, an English-language abstract (which includes a patent family search) is provided to serve as a brief statement of relevance. See also the discussion of JP 59-031707 below.

FR 2,737,118 corresponds to Grollier et al. U.S.P. 6,163,332, a copy of which is provided to serve as an English translation. In addition, an English-language abstract (which includes a patent family search) is provided to serve as a brief statement of relevance. See also the discussion of JP 9-040548 below.

JP 58-128318 corresponds to Augstein et al. U.S.P. 4,917,897 and EP 0084898; copies of both the U.S. and EP documents are enclosed to serve as English translations. In

addition, an English-language abstract (which includes a patent family search) is provided to serve as a brief statement of relevance.

JP 59-031707 corresponds to FR 2,521,565 and Redziniak et al. U.S.P. 4,508,703, a copy of which, as noted above, is provided to serve as an English translation. An English abstract/patent family search is provided to serve as a brief statement of relevance.

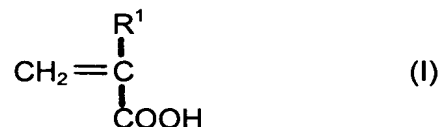
JP 61-100521 corresponds to EP 0179430 and to Chiesi et al. U.S.P. 4,824,841, copies of which are provided to serve as English translations. An English abstract/patent family search is also provided to serve as a brief statement of relevance.

JP 61-183224 has no English language counterpart and applicants do not have an English translation. An English abstract/patent family search is enclosed as a brief statement of relevance. This citation relates to a dispersion of an antibacterial agent comprising:

- (A) 2-mercaptopyridine-N-oxide polyvalent metal salt particles containing more than or equal to 50% by weight of particles having less than or equal to 0.2  $\mu\text{m}$ ;
- (B) (meth)acrylic acid/styrenesulphonic acid copolymer salt;
- (C) one or more protective colloid-forming substances selected from (i) water-soluble nonionic cellulose ester, (ii) polyoxyalkylene-hardened castor oil and (iii) (meth)acrylate/(meth)acrylic acid copolymer or its salt; and
- (D) water and alcohol.

JP 63-185438 corresponds to EP 0268164, which is in English and is provided to serve as an English translation. The enclosed English-language abstract/patent family search serves as a brief statement of relevance.

JP 4-039312 has no English-language counterpart and applicants do not have an English translation. An English-language abstract/patent family search is provided to serve as a brief statement of relevance. This citation relates to a cosmetic composition said to have superior emulsifying stability, useful in sunscreen compositions, comprising a crosslinked acrylic polymer which is formed from 10 parts by weight of at least one monomer having the formula (I) and 0.02 to 2 parts by weight of monomer having the following formula (II) as a copolymerizable fraction, and which has crosslinked points in said copolymer:





wherein R<sup>1</sup> represents a hydrogen atom or methyl group, and R<sup>2</sup> represents an alkyl group having 8 to 20 carbon atoms.

It is disclosed that the crosslinked acrylic polymer can:

1. form an emulsion having various viscosities and being stable in a wide pH range, without using any surfactants;
2. form a stable emulsion comprising various amounts, for example 5 to 40% of oils;
3. emulsify various oils such as most oils and waxes including silicone oils, long chain alkyl esters, liquid paraffin, and natural waxes;
4. make emulsification easy; and
5. have thickening effects even if it is in very low amounts, and form a gelling suspension or emulsion.

JP 5-097644 has no English-language counterparts. A copy of a machine-made English translation is enclosed. Applicants also enclose an English abstract/patent family search to serve as a brief statement of relevance. Claim 1 of the Japanese document claims a UV protection cosmetic composition comprising

- (A) alkyl-modified carboxyvinyl polymer;
- (B) powder insoluble in water and oil;
- (C) lipophilic UV absorbent; and
- (D) water.

It is disclosed that the alkyl-modified carboxyvinyl polymer is an aqueous thickener, has dispersing property of oil in water, and is formed from copolymerization of the following (a) to (c) (for example, Carbopol 1342, Pemulen TRI, and Pemulen TRII (sold by Goodrich):

- (a) 95.9 to 98.8% by weight of olefinically-unsaturated carboxylic monomer;
- (b) 1 to 3.5% by weight of ester of acrylic acid or methacrylic acid with alcohol having 10 to 30 carbon atoms; and
- (c) 0.1 to 0.6% by weight of olefinically-polyfunctional monomer (crosslinker).

JP 7-149621 has no English counterparts. A copy of a machine-made English translation is enclosed. Applicants also enclose an English abstract/patent family search to serve as a brief statement of relevance. This citation relates to an emulsified composition, comprising 30 to 80% by weight of moisturizer, 1 to 50% by weight of oily ingredients, and

an alkyl-modified carboxyvinyl polymer as an emulsifying agent. As the alkyl-modified carboxyvinyl polymer, Carbopol 1342, Pemulen TRI, and Pemulen TRII (sold by Goodrich) are mentioned.

JP 7-187950 has no English-language counterpart. Applicants enclose a machine-made English translation. In addition, an English abstract/patent family search is provided as a brief statement of relevance. This citation relates to a cosmetic composition in the form of an O/W emulsion, comprising:

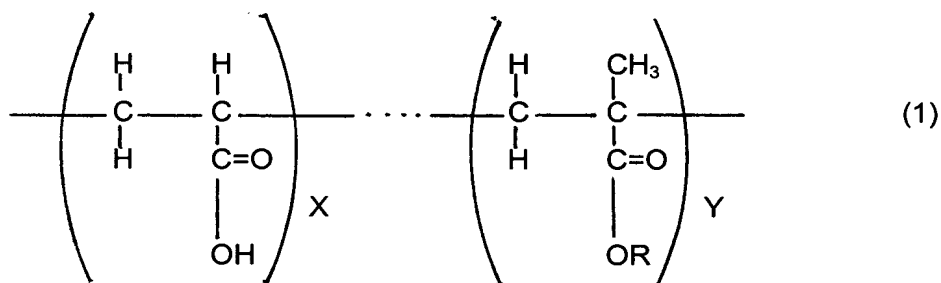
- (a) 0.01 to 3.0% by weight of alkyl-modified carboxyvinyl polymer;
- (b) 1 to 60% by weight of oily ingredient;
- (c) 1 to 40% by weight of silica-coated powder; and
- (d) 30 to 95% by weight of water.

As the alkyl-modified carboxyvinyl polymer, Carbopol 1342, Pemulen TRI, and Pemulen TRII (sold by Goodrich) are mentioned.

JP 7-206629 has no English-Language counterpart. Applicants are providing a machine-made translation. Also, an English abstract/patent family search is provided as a brief statement of relevance. This citation relates to an emulsifying composition, comprising 3 to 20% by weight of silicone, 3 to 20% by weight of solid fat and/or semisolid fat, and 0.1 to 1.0% by weight of C<sub>10-30</sub> alkyl acrylate crosspolymer and/or acrylic acid-long chain alkyl methacrylate copolymer, relative to the total weight of the composition, wherein the weight ratio of said silicone to said solid fat and/or semisolid fat is 2:1 to 1:2, and wherein the total weight of said silicone and said solid fat and/or semisolid fat is 40 to 80% by weight relative to the total weight of the lipophilic ingredients. As the C<sub>10-30</sub> alkyl acrylate crosspolymer, Pemulen TR-1 and Pemulen TR-2 (sold by Goodrich) are mentioned, and as the acrylic acid-long chain alkyl methacrylate copolymer, Carbopol 1342 (sold by Goodrich) is mentioned.

JP 7-241457 has no English counterparts. A machine-made English translation is provided herewith. An English abstract/patent family search is also provided to serve as a brief statement of relevance. This citation relates to an emulsifying composition, comprising cyclodextrin and/or cyclodextrin derivative, oily ingredient, and alkyl-modified carboxyvinyl polymer. As the alkyl-modified carboxyvinyl polymer, Carbopol 1342, Pemulen TRI, and Pemulen TRII (sold by Goodrich) are mentioned.

JP 8-003016 has no English counterparts. A machine-made English translation is enclosed. Applicants are also providing an English abstract/patent family search to serve as a brief statement of relevance. This citation relates to a cosmetic composition, comprising acrylic acid-alkyl methacrylate copolymer having the following formula (1), spherical powder, and a volatile silicone:



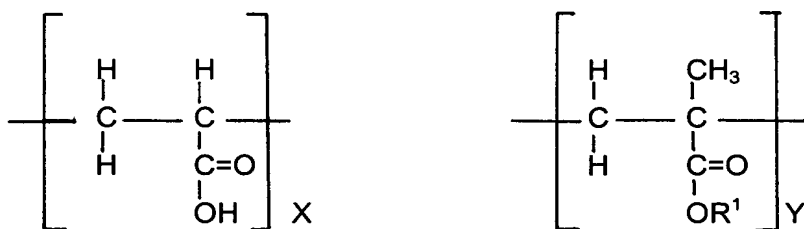
wherein R represents an alkyl group having 10 to 30 carbon atoms, X is 80.0 to 99.9 mol%, and Y is 0.1 to 20.0 mol%. As the acrylic acid-alkyl methacrylate copolymer, Pemulen TR-1 and Pemulen TR-2 (sold by Goodrich) are mentioned. The materials are said to impart a wet feeling in use without oilness/stickiness and to have high moisture-retaining effects.

JP 8-034719 has no English counterparts. Applicants are providing a machine-made English translation; in addition, an English abstract/patent family search is provided to serve as a brief statement of relevance. This citation relates to a cosmetic composition in the form of an O/W emulsion which is said to have superior UV protection effects, and excellent holding and water-repellency, comprising silicon carbide and acrylic polymer. The silicon carbide is not used as a pigment but as a UV absorbent, and is preferably a spherical particle having 0.01 to 100  $\mu\text{m}$ , especially 0.1 to 50  $\mu\text{m}$ , of average particle size. As the acrylic polymer, Carbopol 907, 910, 934, 934-P, 940, 941, 954, 980, 981, 1342, 1382, 2984, and 5984, Pemulen TR-1 and TR-2 (which are sold by Goodrich), Hypam SA-100H, SR-150H, SS-201, QT-100 (which are sold by Lipo Chemical), AQUPEC HV-501, HV-504, and HV-505 (which are sold by Sumitomo Seika) are mentioned.

JP 9-040548 corresponds to Grollier et al. U.S.P. 6,136,332, a copy of which is provided to serve as an English translation. In addition, applicants are also providing an English-language abstract/patent family search to serve as a brief statement of relevance.

JP 9-066097 has no English language counterparts. Applicants do not have an English translation. An English abstract/patent family search is provided as a brief statement of relevance. This citation relates to a coating material for afflicted skin treatment, comprising cyclic AMP and/or its derivative in a matrix consisting of collagen, gelatin, hyaluronic acid, chitosan, alginic acid or its salt.

JP 9-249543 has no English-language counterparts. Applicants are providing a machine-made English translation. Moreover, an English abstract/patent family search is provided as a brief statement of relevance. This citation relates to a jelly cosmetic composition, comprising hydrophobic oil-absorbent powder, a basic material, and alkyl-modified carboxyvinyl polymer having the following formula:



wherein R<sup>1</sup> represents an alkyl group having 10 to 30 carbon atoms, X is 80.0 to 99.9 mol%, and Y is 0.1 to 20.0 mol%.

The hydrophobic oil-absorbent powder is a spherical particle having an average particle size of 0.5 to 50  $\mu\text{m}$ , preferably 1 to 20  $\mu\text{m}$ , and is exemplified by porous Nylon powders such as Orgasol 2002 (sold by Elf Atochem); dimethyl silicone-crosslinked elastomers such as Trefil E-506C (sold by Toray Dow Silicone); poly(methyl) methacrylate)s such as Microsphere M, M-100, M-300, and M-400 (sold by Matsumoto Ushi); and methacrylate copolymers such as Polytrap (sold by Dow Corning); and porous vinyl polymers. As the alkyl-modified carboxyvinyl polymer, Carbopol 1342, Pemulen TR-1, and Pemulen TR-2 (sold by Goodrich) are mentioned.

JP 10-130119 has no English-language counterparts. Applicants are providing a machine-made English translation. An English abstract/patent family search is provided to serve as a brief statement of relevance. This citation relates to a skin preparation for external use, in particular for the treatment of acne, obtained by formulating (A) at least one selected from aluminum magnesium silicate and bentonite with (B) at least one selected from glycerol and betaine.

JP 10-265405 has no English-language counterparts. Applicants are providing a machine-made English translation. An English abstract/patent family search is provided to serve as a brief statement of relevance. This citation relates to a skin preparation for external use comprising a base material, a pharmaceutically active ingredient and also insulin.

WO 96/11002 corresponds to Miyata et al. U.S.P. 5,837,735 and also EP 0 782 855, copies of both of which are enclosed to serve as English translations. An English abstract/patent family search is provided to serve as a brief statement of relevance.

WO 97/02090 corresponds to Watanabe et al. U.S.P. 5,827,920 and EP 0 779 097, copies of which are provided as English translations. An English abstract/patent family search is also provided to serve as a brief statement of relevance.

It is respectfully requested that the Examiner consider this statement and cited references and that an Examiner-initialed copy of the accompanying Form PTO-1449 be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date July 28, 2005

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# **SECOND INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

**Complete if Known**

<b>Sheet</b> <b>1</b> <b>of</b> <b>1</b>			<b>Application Number</b>	09/881,686
			<b>Filing Date</b>	June 18, 2001
			<b>First Named Inventor</b>	Sandrine SEGURA et al.
			<b>Examiner Name</b>	Shengjun Wang
			<b>Attorney Docket Number</b>	034227-445

## **U.S. PATENT DOCUMENTS**

Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
	4,508,703		Redziniak et al.	04-02-1985
	6,136,332		Grollier et al.	10-24-2000
	4,917,897		Augstein et al.	04-17-1990
	4,824,841		Chiesi et al.	04-25-1989
	5,837,735		Miyata et al.	11-17-1998
	5,827,920		Watanabe et al.	10-27-1998

## **FOREIGN PATENT DOCUMENTS**

Examiner Initials	Document Number	Kind Code (if known)	Country	Date of Publication (MM-DD-YYYY)	STATUS						
					Translation	Partial Translation	Eng. Lang. Summary	Search Report	IPER	Abstract	Cited in Spec
	0 084 898	A2	EP	08-03-1983							
	0 179 430	A2	EP	04-30-1986							
	0 268 164	A2, B1	EP	05-25-1988							X
	0 779 097	A1	EP	06-18-1997							
	0 782 855	A1	EP	07-09-1997							
	2,521,565		FR	08-19-1983	X					X	
	2,737,118		FR	01-31-1997	X					X	
	58-128318	A	JP	07-30-1983	X					X	
	59-031707	A	JP	02-20-1984	X					X	
	61-100521	A	JP	05-19-1986	X					X	
	61-183224	A	JP	08-15-1986						X	
	63-185438	A	JP	08-01-1988	X					X	X
	4-039312	A	JP	02-10-1992						X	
	5-097644	A	JP	04-20-1993		X				X	
	7-149621	A	JP	06-13-1995		X				X	
	7-187950	A	JP	07-25-1995		X				X	
	7-206629	A	JP	08-08-1995		X				X	
	7-241457	A	JP	09-19-1995		X				X	
	8-003016	A	JP	01-09-1996		X				X	
	8-034719	A	JP	02-06-1996		X				X	
	9-040548	A	JP	02-10-1997	X					X	
	9-066097	A	JP	03-11-1997						X	
	9-249543	A	JP	09-22-1997		X				X	
	10-130119	A	JP	05-19-1998		X				X	
	10-265405	A	JP	10-06-1998		X				X	
	96/11002	A1	WO	04-18-1996	X					X	
	97/02090	A1	WO	01-23-1997	X					X	

## **NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
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Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.